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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/463,352 01/21/00 GOUDSMIT

J T/97300 US

EXAMINER

HM12/0214

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SISSON, B  
ART UNIT PAPER NUMBER

1655  
DATE MAILED:

02/14/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

### Office Action Summary

Application No.

09/463,352

Applicant(s)

GOUDSMIT ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montagnier et al., in view of Research Genetics.

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Montagnier et al., column 19, third paragraph, bridging to column 20, disclose primers for detecting HIV-1 and methods of doing same. At column 19, last paragraph, bridging to column 20, first two lines, Montagnier et al., teach explicitly of directing primers to conserved regions and that just such a region can be found in the LTR. It is noted that the LTR is the very region from which applicant has selected the instantly claimed primers/probes; see the response of 26 December 2000, page 7, lines 13-15, wherein is stated:

The primers of the present invention are not from the GAG region, but instead are from the long terminal repeat (LTR) of HIV-1."

Accordingly, Montagnier et al., are directing the public to this very region for the selection of primers and probes. Furthermore, they provide motivation in selecting sequences that allow for the detection of multiple isolates when they teach that the LTR is "highly conserved."

Montagnier et al., column 20, second paragraph, teach that RT-PCR can be practiced and that such allows for the detection of viral sequences in individuals before they seroconvert.

Research Genetics, through their advertisement, disclose for sale software that allows the ordinary artisan to select primer and probe sequences of desired specificity, length, GC content, secondary structure characteristics, etc.

It would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to have used the software of Research Genetics with the teachings of Montagnier et al., so to select primers and probes from the LTR region of HIV-1 and to have used same in an amplification or transcription-based method of detecting HIV-1 sequences. In view of the explicit teachings by Montagnier et al., as to the LTR being "highly conserved," the

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ordinary artisan would have expected the primers and probes to permit the detection of many, if not all, HIV-1 isolates.

Applicant's statements to their ability to detect all known isolates of HIV-1 through the use of their primers/probes, in light of the explicit teachings of Montagnier et al., do not rise to the level of a an unexpected and non-obvious quality. Accordingly, the rejection under 35 USC 103(a) has not been found to be lessened by a secondary consideration.

### *Conclusion*

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US Patent 5,306,631 (Harrison et al.) column 20, last paragraph, bridging to column 21.
- b. US Patent 5,576,176 (Adams et al.) column 8, last two paragraphs, bridging to column 9.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

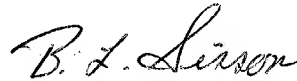
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1655

BLS  
February 9, 2001